

What is claimed is:

1. Apparatus for forming an array of microneedle structures in a polymer material, said apparatus comprising a mold assembly including at least one bore therethrough having a cavity therein defining the shape of the finished microneedle shape to be formed therein, said bore having an inlet opening and an exit opening;
5 means for locating the polymer to be formed at one end of said cavity;
means for introducing fluid into said inlet opening of said bore and into said cavity;
and
exhaust means communicating with said exit opening of said bore, whereby
10 introducing said fluid through said polymer causes said polymer to assume the shape of said cavity and said fluid forms a hollow channel to define a needle-like structure in said polymer as said fluid is exhausted through said cavity and said bore.
2. The apparatus set forth in claim 1, wherein said mold assembly includes upper and lower manifolds separated by a fluid-tight gasket disposed
15 therebetween, and said mold forming cavity is in said upper manifold.
3. The apparatus set forth in claim 2, and further including a gas permeable membrane disposed between said gasket and said cavity with said polymer to be disposed above said gas permeable membrane.
4. The apparatus of claim 2, wherein said lower manifold has a gas inlet
20 communicating with an internal cavity that feeds to said at least one bore.
5. The apparatus of claim 2, wherein the polymer is a UV-curable polymer and said upper manifold is formed with a transparent or translucent section to allow such polymer to be exposed to UV light while still in said mold cavity for curing said formed polymer.

6. The apparatus of claim 1, wherein at least a portion of said mold assembly is made of a polymeric construction.

7. The apparatus of claim 1, wherein at least a portion of said mold assembly is of metallic construction.

5 8. The apparatus of claim 1, wherein the fluid introduced constitutes a gas in a pressure range from less than 1 to 15-20 kilopascals per square centimeter (1 psi to 15-20 psi).

9. The apparatus of claim 1, and further including means for providing a vacuum pressure at the outlet side of said bore to draw said fluid through said
10 polymer forming the microneedle channel.

10. The apparatus of claim 1, wherein said cavity for forming each said microneedle comprises a cavity of a height of approximately 160 microns (.0064 inches) having a base diameter of approximately 50 microns (.002 inches) and each of said microneedles is spaced approximately 300 microns (.012 inches) apart center-to-
15 center.

11. The apparatus of claim 1, wherein said structure defining said microneedle-shaped cavity comprises a mold form disposed in said mold assembly.

12. The apparatus of claim 11, wherein said cavity in said mold assembly for forming said microneedle structure is tapered from one end to the other.

20 13. The apparatus of claim 12, wherein said small opening of said tapered cavity is directed toward said fluid exit.

14. The apparatus of claim 12, wherein said smaller opening of said tapered cavity is directed toward said fluid inlet.

15. The apparatus of claim 1, wherein said gas permeable membrane is

formed of a polyester fabric.

16. The apparatus of claim 1, wherein said gasket is in the form of a rigid strip of material having openings therein aligned with said bore and said cavity.

17. The apparatus of claim 1, wherein said gasket is comprised of a
5 silicone rubber.

18. The apparatus of claim 1, wherein said structure defining said microneedle-shaped cavity further comprises a mold form disposed between said upper and lower manifolds and above said gas permeable member.

19. A method of forming an array of microneedle structures in a polymer
10 material, comprising the steps of placing a polymeric material in a mold form having a cavity therein with an inlet opening and an exit opening in said cavity;

forcing a fluid under pressure through said polymeric material thereby causing the polymeric material to assume the shape of the mold form and continuing to force said fluid through the polymer until the fluid material exits from the outlet opening of
15 said cavity, thereby forming a hollow channel through the polymer to define the microneedle structure formed in said cavity.

20. The method according to claim 19, further including the step of curing said polymeric material in the form of said microneedle structure while said polymer is in said mold assembly.

21. The method of claim 19, wherein the fluid introduced constitutes a gas in a pressure range from less than 1 to 15-20 kilopascals per square centimeter (1 psi to 15-20 psi).

22. The method of claim 19, wherein said polymer material is in the form of a thermoplastic film; and further including the step of liquefying said film by heat

and then allowing said film to cool and solidify in said mold cavity after taking on the shape of the mold form and having the through channel formed therein to define the microneedle shape.

23. The method of claim 19, wherein said polymer consists of a powder,
5 and comprising the steps of liquefying said powder by heat and then cooling and solidifying said polymer material after it has taken the shape of said mold form and having the channel formed therein to form said microneedle.

24. The method of claim 19, and further including the step of providing a
10 means for exhausting the fluid passing through the polymer at the outlet end of said bore.

25. The method according to claim 19, wherein said mold form can consist of upper and lower manifolds halves and a support sheet is provided in the form of a porous material permitting the gas to pass through the lower manifold to the gas permeable member while supporting the mold and polymer substrate.

15 26. The method set forth in claim 19, wherein the polymer is inserted in a liquid form and is approximately 125 to 250 microns (.005 to .010 inches thick) and further including the step of curing said liquid polymer to form said microneedles.

27. The method of claim 19, wherein said polymer material comprises either a urethane, polysulfone, nylon, polycarbonate or acrylic.

20 28. The process of claim 19, wherein the thickness of the wall of said microneedle may be varied by varying the rate of the gas flow through said polymer or by varying the viscosity of said polymer.

29. The method of claim 19, wherein said fluid is an inert gas.

30. The method of claim 19, wherein the through channel formed in said

microneedle is in the range of 5 to 25 microns (.0002 to .001 inches) approximate diameter.

31. The method of claim 19, wherein the microneedle through channel is in the range of 140-200 microns tall (.0056 to .0080 inches) and the walls of said
5 microneedle are in the range of 5 to 25 microns (.0002 to .001 inches).

32. The method of claim 19, wherein the mold forming cavity is tapered from one end to the other.

33. The method of claim 32, wherein the fluid under pressure is first passed through the large opening end of said tapered cavity.

10 34. The method of claim 32, wherein the fluid under pressure is first passed through the narrow opening end of said tapered cavity.

35. The method of claim 32, wherein the polymer is cured while the gas is flowing through the channel.

36. An apparatus for forming an array of microneedle structures in a
15 polymer material, said apparatus comprising a mold assembly having an upper manifold and lower manifold, each of said manifolds being adapted to be positioned in airtight relation relative to one another, the upper manifold having at least one cavity formed therein;

at least one bore in said lower cavity feeding through to a bore in said cavity
20 and through said upper manifold;

an inlet port feeding said bore in said lower manifold;

an exit port for exhausting said upper cavity via said bore in said upper manifold;

a gas impervious gasket disposed between said upper and lower manifolds;

a gas permeable membrane adapted to be positioned between said upper and lower manifolds.

37. The apparatus of claim 36, wherein said upper manifold includes a plurality of mold forming cavities therein, each of said mold forming cavities being
5 configured to provide a microneedle-like structure therein, with the height of said needle being approximately 160 microns and having a base diameter of approximately 50 microns and the spacing of at least two of said microneedle assemblies being disposed approximately 300 microns from one another center-to-center.

38. The apparatus of claim 36, wherein the through hole or channel formed
10 by said microneedle cavity is of a tapered configuration.

39. The apparatus of claim 38, wherein said gas permeable membrane is formed of a polyester fabric.

40. The apparatus of claim 38, wherein said gasket is in the form of a rigid strip of material having openings therein aligned with said bore and said cavity.

15 41. The apparatus of claim 38, wherein said gasket is comprised of a silicone rubber.

42. The apparatus of claim 38, wherein said structure defining said microneedle-shaped cavity further comprises a mold form disposed between said upper and lower manifolds and above said gas permeable member.

20 43. An apparatus for continuously forming an array of microneedle structures in a polymer material, said apparatus comprising

a first elongated flexible and permeable belt-like member;

means for generating gas under pressure through said first belt;

means for moving said belt-like member past said gas generating means;

means for heating said gas means;

means for placing a film of polymer material on said first belt prior to
approaching said gas generating means;

a continuous flexible mold form defining an array of microneedle cavities
5 therein and adapted to be in contact with said polymer film;

second belt flexible gas permeable means disposed above said mold form to
permit heated gas under pressure to pass through said film and melt the polymer
material and to force the molten material into said needle-like cavities and to exhaust
said gas past said second belt.